## REMARKS

A check for the requisite fee for a two month extension of time accompanies this response. Any fees that may be due in connection with this application may be charged to Deposit Account No. Deposit Account No. 06-1050. If a Petition for extension of time is needed, this paper is to be considered such Petition. A change of address for the undersigned accompanies this response.

Applicant thanks Examiner for the courtesy extended in granting the interview of February 27, 2004. In the interview, the parties came to an agreement that claim 20 is allowable. Further, amendments of claim 18 to clarify its intended scope were agreed upon. Claim 18 has been so-amended and should now be in condition for allowance. Claim 21 also is amended in a manner consistent with the Examiner interview of February 27, 2004. The amendments to claims 18 and 21 are intended to clarify the illuminating and measuring steps and are not intended to alter the scope of the claims. No new matter has been added by the amendments.

Claims 1, 3-9 and 11-32 are pending in this application. Claims 1, 3-9, 11-17, 22-28, 31 and 32 are allowable. Pursuant to the telephonic interview, the remaining rejected claims also should now be in condition for allowance.

**THE REJECTION OF CLAIMS 18 AND 21 UNDER 35 U.S.C. §103(a)**

Claims 18 and 21 are rejected under 35 U.S.C. §103(a) as being unpatentable over Connolly (International PCT application No. WO 96/13707) in view of Augstein (U.S. Patent No. 5,665,310). This rejection is respectfully traversed.

**Relevant law**

To establish a *prima facie* case of obviousness, prior art references when combined must teach or suggest all the claim limitations. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Another requirement to establish a *prima facie* case of obviousness is a teaching or suggestion to modify or combine the references to arrive at the claimed subject matter. "Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so." *In re Fritch*, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (emphasis original). "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, at 1783-84. Without the teachings of the prior art suggesting the combination, it is impermissible to pick and choose among isolated disclosures in the prior art to conclude that the claimed invention is obvious. *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

**Claims 18 and 21**

Claims 18 and 21 are amended herein to more clearly recite that the same measuring and illuminating steps performed at the first position on the surface of a test strip also are performed at additional positions. Hence, as intended, Claim 18 is directed to a method for reading a surface of a test strip having an image, by moving a reader head in a reflectance reader to a first position over the surface comprising the image; measuring a first amount of light reflected from the surface comprising the image; uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; repeating the same measuring and illuminating steps performed at the first position on the surface of a test strip at additional positions on the surface until the image on the surface of the test strip is scanned; and determining an intensity or shape of the image. Claim 21 is directed to a method for reading a

surface of a test strip having an image, by: moving a reader head in a reflectance reader to a first position over the surface comprising the image; measuring a first amount of light reflected from the surface comprising the image; uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface; uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface; and moving the reader head in a stepwise fashion to a plurality of positions over the test strip, where the same measuring and illuminating steps performed at the first position on the surface of a test strip are repeated at each of the plurality of positions to determine an intensity or shape of the image.

**Connolly**

Connolly teaches a diagnostic test strip for use in an analyzer for measuring analyte in a sample. The test strip includes an elongated body having first and second ends and a hinged portion between the ends so that the first end is foldable over the second end or the body. The first and second ends each have an opening aligned with each other when the first end is folded. A carrier layer means includes a separating layer for whole blood cells.

In methods that use the test strip, the density of a color reaction is determined using a spectrophotometric device that includes a hand-held housing, a test strip holding region that is located above three light detectors or sensors each disposed within a port. During test operation, a test strip is inserted into the holding region so that the test strip openings are located adjacent to the ports. Multiple wavelengths can be used to irradiate the strip in conjunction with multiple chromophores, or with different angles of emission when the light emitters are at different angles with the surface of the test strip.

Light sensors take a reading from the exposed portions of the strip. In operation, as a test strip is inserted into the device, the instrument detects a change in the exposed portion and identifies the test type by reading a color

coded label. A sample is then applied and the measurement cycle commences. A measurement cycle is carried out to ensure that the proper amount of sample was added to the test strip. A measurement cycle is carried out to measure the end of the reaction on the test strip. The instrument measures the density of the reaction and determines the concentration.

**Augstein**

Augstein describes a measuring head for evaluating a test strip, where the measuring head rests on a spacer and thereby ensures a defined distance between the measuring head and the surface of the test strip. The test strip of Augstein has separate and different test fields separated by measuring openings, where the different test fields have different thicknesses, and the different test fields serve to evaluate different analytes. In examining various test fields, the measuring head moves relative to the test strip, where the measuring head is guided by the spacer to maintain a constant distance between the surface of each test field and the measuring head. Evaluation of each test field with different wavelengths can be carried out using several measuring heads, where each head uses one specific type of radiation.

**Analysis**

During the Examiner interview of February 27, 2004, it was agreed that Connolly and Augstein, neither alone or combined, teaches or suggests a method in which the same measuring and illuminating steps performed at the first position on the surface of a test strip also are performed at additional positions. Accordingly, no combination of the cited references render the methods of claims 18 and 21 as *prima facie* obvious.

**THE REJECTION OF CLAIMS 19 AND 20 UNDER 35 U.S.C. §103(a)**

Claims 19 and 20 are rejected as being unpatentable over Connolly in view of Augstein under 35 U.S.C. §103(a) because Connolly teaches an optical reading apparatus that contains a separate readhead, which does not move, and Augstein teaches an apparatus that contains a moving measuring head for

analyzing a sample, and the cited references allegedly teach or suggest transmitting light at an angle normal to the test strip surface, and measuring light reflected normally from the surface. This rejection is respectfully traversed.

**Claims 19 and 20**

Claim 19 is directed to a method for reading a surface of a test strip having an image, by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface comprising the image, transmitting light of a first wavelength onto the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface, and transmitting light of a second wavelength onto the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface.

Claim 20 is directed to a method for reading a surface of a test strip comprising an image, by, with a reader head in a reflectance reader at a first position over the surface comprising the image, measuring a first amount of light reflected from the first position of the surface comprising the image; transmitting light of a first wavelength onto the first position of the surface at an angle normal to the surface, and measuring a second amount of light reflected normally from the surface; transmitting light of a second wavelength onto the first position of the surface at an angle normal to the surface, and measuring a third amount of light reflected normally from the surface; moving the reader head to a second position over the surface comprising the image; measuring a fourth amount of light reflected from the second position on the surface comprising the image; transmitting light of the first wavelength onto the second position of the surface at an angle normal to the surface, and measuring a fifth amount of light reflected normally from the surface; transmitting light of the second wavelength onto the second position of the surface at an angle normal to the surface, and measuring a sixth amount of light reflected normally

from the surface; and determining a parameter correlated with an intensity or shape of the image.

**Analysis**

During the Examiner interview of February 27, 2004, all parties came to an agreement that Connolly and Augstein, neither alone or combined, teaches or suggests a method in which at a first position light of first and second wavelengths are transmitted normal to the surface of a test strip and first, second and third amounts of light reflected normally from the surface are measured, and at a second position light of first and second wavelengths are transmitted normal to the surface of a test strip and fourth, fifth and sixth amounts of light reflected normally from the surface are measured. Accordingly, it was agreed that no combination of the cited references render the method of claim 20 as *prima facie* obvious. In view of the discussion in the Examiner interview, the obviousness rejection as it applies to claim 20 is now moot. Accordingly, the following comments are directed to the rejection as it applies to claim 19.

The references, alone or combined, do not teach or suggest a method that includes transmitting light at an angle normal to the surface. Furthermore, the cited references must teach or suggest the desirability of any modification. In this instance the cited references do not teach or suggest such modification and in, fact, such modification would be contrary to the teachings of Connolly. Therefore, the modification cannot be a matter of routine optimization.

**The combined references do not teach or suggest all claim limitations**

There is no teaching or suggestion in Connolly or Augstein of transmitting light onto the surface at an angle normal (or perpendicular) to the surface. Connolly teaches positioning the detector and light emitters at different angles to correct for problems in positioning a test strip. Connolly never teaches or suggests transmitting light onto the surface at an angle normal to the surface. Augstein is silent regarding angular positioning of a light source. Thus,

Augstein, when combined with Connolly, contributes nothing regarding angular positioning of a light source. Accordingly, Connolly and Augstein, alone or combined, do not teach or suggest all elements of claim 19.

**The references would not have lead to an optimization in which light is transmitted normal to the surface of a test strip**

The teachings of the cited references would not have motivated one of ordinary skill in the art to modify the methods of the references by routine optimization in order to arrive at a method in which light is transmitted at an angle normal to the surface of a test strip. Connolly consistently teaches away from transmitting light onto the surface at an angle normal to the surface. For example, Connolly teaches angular positioning of the detector and light emitters to correct for problems in positioning a test strip, at page 5, lines 7-17:

> Multiple wavelengths and different angles are used to correct possible problems in positioning the strip in the instrument. If the detector is at "0" angle and the emitters of the same or different wavelengths are at different angles (e.g., one at 40° and one at 50°), the tilting of a surface will positively contribute to one reading while it will contribute in a negative manner to the other reading thus it is able to cancel the error presented by the angle presentation of the surface. These same measurement methods can be used to eliminate interferences from substances such as bilirubin and others.

Connolly repeats these teachings at page 21, line 28, through page 22, line 8. In a further example, Connolly recites a test instrument with a light source emitting light at multiple angles at independent claim 19. In yet another example, Connolly in Figure 5 depicts light sources emitting light onto the test strip at non-perpendicular angles. Thus, throughout the publication by Connolly, there are teachings of positioning the light emitters at non-perpendicular angles, and the benefits expected from such positioning. Further, Connolly never teaches or suggests any angular adjustments that could lead to transmitting light at an angle normal to the surface. Accordingly, Connolly consistently teaches away from transmitting light onto the surface at an angle normal to the

surface. Therefore, there would have been no way for one of ordinary skill in the art to be motivated by the teachings of Connolly to modify the angle of light emitters to a position normal to the surface.

As noted, Augstein is silent regarding angular positioning of a light source. Since Connolly consistently teaches away from the alleged optimization, and Augstein is silent, the references cannot be combined to result in the instantly claimed methods.

The Office Action asserts that it would have been no more than routine optimization for one skilled in the art to arrive at a method that included transmitting light onto the surface at an angle normal to the surface. Optimization of a variable in a prior art reference does not render a claim obvious when the prior art in any material way teaches away from the claimed invention. *In re Geisler* 43 USPQ2d 1362, 1365 (Fed. Cir. 1997); *In re Malagari*, 182 USPQ 549, 553 (1974 CCPA). Connolly repeatedly teaches away from transmitting light onto the surface at an angle normal to the surface, and never teaches toward the optimization asserted in the Office Action. Accordingly, the teachings of Connolly cannot be used to render obvious a method that includes transmitting light onto the surface at an angle normal to the surface.

**All teachings of Connolly must be considered**

The Office Action characterizes the above teachings of Connolly as "only an example" and concludes that Connolly satisfies the "transmitting light ... normal to the surface" claim element because Connolly does not exclude the claim element. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984); MPEP §2141.02. Connolly at various locations throughout the publication, consistently teaches transmitting light at non-perpendicular angles. Each of these teachings must be considered in any determination of obviousness of claim 19. Connolly never

teaches or suggests angular modifications that would motivate one of ordinary skill in the art to transmit light at an angle normal to the surface. Thus, the teachings of Connolly, considered in their entirety, only lead away from the method of claim 19. Accordingly, the teachings of Connolly cannot be used to render obvious the method of claim 19.

**THE REJECTION OF CLAIMS 29 AND 30 UNDER 35 U.S.C. §103(a)**

Claims 29 and 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Connolly and Augstein, and in further view of Hernicz (U.S. Patent No. 4,659,229) because Connolly, when combined with Augstein, allegedly teaches reading a test strip at multiple wavelengths and a movable read head, and Hernicz allegedly teaches a reader head with an aperture and use of fiberoptic bundles to illuminate a sample and measure reflected light. This rejection is respectfully traversed.

**The Claims**

Claims 29 and 30 are directed to methods for reading the surface of a test strip having an image by moving a reader head in a reflectance reader to a first position over the surface having the image, measuring a first amount of light reflected from the surface, uniformly illuminating the surface with light of a first wavelength, and measuring a second amount of light reflected from the surface, and uniformly illuminating the surface with light of a second wavelength, and measuring a third amount of light reflected from the surface. The methods further include emitting the light of the first wavelength from a light emitting diode, transmitting the emitted light of the first wavelength through a first fiberoptic bundle to the surface of the test strip, and transmitting the second amount of light reflected from the surface of the test strip through a second fiberoptic bundle to a photodetector, where claim 30 also includes emitting the light of the second wavelength from a second light emitting diode, transmitting the emitted light of the second wavelength through a third fiberoptic bundle to the surface of the test strip, and transmitting the third

amount of light reflected from the surface of the test strip through the second fiberoptic bundle to the photodetector.

**Teachings of the cited references**

The teachings of Connolly and Augstein are discussed above. Neither Connolly nor Augstein singly nor in combination thereof teaches or suggests a method using fiberoptic bundles.

**Hernicz**

Hernicz teaches a reader head with reduced height sensitivity that measures reflectance from a sample. The reader head is configured such that the upper portion of the inner surface is hemispherically shaped and the lower portion is conically shaped. In the method of Hernicz, a sample is indirectly exposed to diffuse light produced by a high intensity flash lamp or continuous incandescent lamp, the light is reflected from the sample surface, and the reflected light is received by a first fiber optic bundle and transferred to a first detector. Light also is reflected from the readhead, and the reflected light is received by a second fiber optic bundle and transferred to a second detector.

Hernicz does not teach or suggest transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip. Hernicz does not teach or suggest transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip. Instead, Hernicz teaches the importance of indirectly and diffusely illuminating the sample.

**Analysis**

A *prima facie* rejection of these claims has not been established because the combination of the cited references does not teach or suggest all claim limitations. Furthermore, there would have been no motivation to have modified the teachings of the cited references to arrive at the claimed methods.

**None of the references teaches or suggests transmitting emitted light through a fiberoptic bundle to a test strip surface**

Hernicz teaches use of fiberoptic bundles to receive light reflected from the test strip, but Hernicz does not teach or suggest transmitting light emitted

from any light source through a fiberoptic bundle to the surface of a test strip. Instead, Hernicz teaches the importance of indirectly and diffusely illuminating the test strip (see, *e.g.*, Abstract of Hernicz). Connolly and Augstein add nothing to that which is lacking in Hernicz because Connolly and Augstein do not teach or suggest anything about fiberoptic bundles. In particular, the teachings of Connolly regarding use of an LED light source add nothing to that which is lacking in Hernicz because Hernicz does not teach or suggest transmitting light emitted ***from any light source*** through a fiberoptic bundle to the surface of a test strip. Accordingly, the three cited references, alone or combined, do not teach or suggest all elements of claims 29 and 30.

**The references provide no motivation to transmit emitted light through a fiberoptic bundle to the surface of a test strip**

The references, alone or combined, provide no motivation for a method that includes transmitting emitted light through a fiberoptic bundle to the surface of a test strip. Hernicz teaches that the reader head is used to diffusely illuminate the test strip. (Hernicz, Abstract, column 4, lines 21-33, and claims 1-5). Hernicz teaches preventing direct illumination of the test strip (Abstract, column 4, lines 57-60, claim 1), and enhancing diffusion of the light used to illuminate the test strip (column 4, lines 16-20, and claims 2 and 5). Hernicz cannot provide motivation to transmit emitted light through a fiberoptic bundle to the surface of a test strip because such a transmission would go against indirect and diffuse illumination of the test strip taught by Hernicz, and result in direct illumination of the test strip, which Hernicz indicates is to be prevented. Thus, the teachings of Hernicz would have motivated one of ordinary skill in the art to avoid transmitting emitted light through a fiberoptic bundle to the surface of a test strip, since such would achieve that which Hernicz teaches should be avoided.

Connolly and Augstein add nothing to that which is lacking in Hernicz because Connolly and Augstein provide no teachings and hence no motivation for any use of a fiberoptic bundle. Accordingly, no combination of references

teaches or suggests transmitting emitted light to a test strip through a fiberoptic bundle.

**The motivation to modify the references asserted in the Office Action is not present in any reference, and is therefore evidence entered by judicial notice**

There is no teaching or suggestion in any of Connolly, Augstein or Hernicz that would have motivated one of ordinary skill in the art to modify the references to a method that includes transmitting emitted light through a fiberoptic bundle to the surface of a test strip. In asserting a motivation to modify the references, the Office Action states that how fiberoptics are used "would be a matter of design choice that one of ordinary skill in the art would recognize". Connolly, Augstein or Hernicz do not teach or suggest such a design choice. Therefore, this statement is an assertion of a fact not taught or suggested by Connolly, Augstein or Hernicz. Accordingly, this statement represents an entry of evidence into the record by judicial notice.

**Evidence entered by judicial notice must be supported by documentary evidence**

In an obviousness rejection, deficiencies of the cited references cannot be remedied by general conclusions about what is "basic knowledge" or "common sense" to one of ordinary skill in the art. *In re Zurko*, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001). With respect to core factual findings in a determination of patentability, an Office Action cannot simply reach conclusions based on its own understanding or experience — or on its assessment of what would be basic knowledge or common sense. Rather, the Office Action must point to some concrete evidence in the record in support of these findings. *Zurko*, at 1697. If an applicant traverses the an assertion of judicial notice, the Examiner must provide documentary evidence in the next Office Action if the rejection is to be maintained. See MPEP §2144.03; 37 CFR §1.104(d)(2).

In accordance with MPEP §2144.03, 37 CFR §1.104(d)(2), and *In re Zurko*, 59 USPQ2d 1693 (Fed. Cir. 2001), Applicant traverses the judicial notice

that transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip "would be a matter of design choice that one or ordinary skill in the art would recognize". This statement alleges the manner in which one of ordinary skill in the art would choose to transmit light onto the surface of a test strip in a method for reading the surface of a test strip. However, methods for transmitting light onto the surface of a test strip are neither basic knowledge nor arise simply from common sense, and methods for transmitting light onto the surface of a test strip fall outside of the expertise of the PTO to determine in the absence of supporting evidence. Methods such as that taught in the reference of record by Hernicz demonstrate that design choice can include avoiding illuminating a test strip with a fiberoptic bundle. Thus, design choice does not necessarily lead to using a fiberoptic bundle to transmit light to a test strip. Further, the only evidence of record that would lead one or ordinary skill in the art to such a design choice are the teachings of the application at issue, which cannot serve as the source for motivation of one of ordinary skill in the art in establishing the claims as *prima facie* obvious. Accordingly, Applicant respectfully requests documentary evidence supporting the design choice asserted by judicial notice.

Hence for all of the reasons above, the Office Action has not set forth a *prima facie* case of obviousness.

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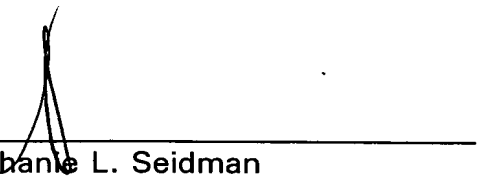
In view of the above remarks and the amendments and remarks of record, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,
FISH & RICHARDSON P.C.

By: 

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